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PRE-APPEAL BRIEF REQUEST FOR REVIEW

Docket Number (Optional)
3713405-01007

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Application Number	Filed
09/854,414	May 10, 2001

First Named Inventor: Gerald Horn

Art Unit	Examiner
1612	Zohreh A. Fay

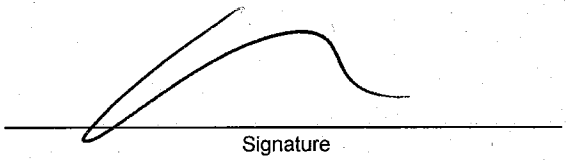
Applicant requests review of the final rejection in the above-identified application. No amendments are being filed with this request.

This request is being filed with a notice of appeal.

The review is requested for the reason(s) stated on the attached sheet(s).
Note: No more than five (5) pages may be provided.

I am the

- ☐ applicant/inventor.
- ☐ assignee of record of the entire interest. See 37 CFR 3.71. Statement under 37 CFR 3.73(b) is enclosed. (Form PTO/SB/96)
- ☑ attorney or agent of record. Registration number 46,541.
- ☐ attorney or agent acting under 37 CFR 1.34. Registration number if acting under 37 CFR 1.34 _____



Signature

Thomas C. Basso
Typed or printed name

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Telephone number

July 13, 2010
Date

NOTE: Signatures of all the inventors or assignees of record of the entire interest or their representative(s) are required. Submit multiple forms if more than one signature is required, see below*.

☐ *Total of _____ forms are submitted.

This collection of information is required by 35 U.S.C. 132. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.11, 1.14 and 41.6. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Mail Stop AF, Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): Gerald Horn
Appl. No.: 09/854,414
Conf. No.: 7675
Filed: May 10, 2001
Title: OPHTHALMIC FORMULATIONS
Art Unit: 1612
Examiner: Zohreh A. Fay
Docket No.: 3713405-01007

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

PRE-APPEAL BRIEF

Sir:

The Pre-Appeal Brief is submitted in reply to the Final Office Action dated January 14, 2010 (Final Office Action). This Pre-Appeal Brief is filed contemporaneously with a "Pre-Appeal Brief Request for Review" and a "Notice of Appeal."

The Pre-Appeal Brief, Notice of Appeal, and Pre-Appeal Brief Request for Review are submitted in response to the rejections of Claims 74-77 as maintained in the Final Office Action. Claims 74-77 are pending in this application. In the Office Action, claims 74, 75 and 77 are rejected under 35 U.S.C. §102 in view of U.S. Patent No. 4,443,441 (Galin I); and claims 74-77 are rejected under 35 U.S.C. §103 in view of Galin I and U.S. Patent No. 5,612,027 (Galin II). Applicant asserts that the Patent Office's anticipation and obviousness rejections in the Final Office Action rise to the level of clear error and make the case proper for pre-appeal review. Moreover, claims 74-77 appear to be provisionally rejected under 35 U.S.C. §101 in view of copending application nos. 10/799,299 and 10/867,144. Considering this rejection is provisional, Applicant elects to address this rejection upon indication of allowance of at least one of the present application and the co-pending patent applications at issue, to the extent even applicable at that time, and thus this response should be considered responsive to the provisional rejections at this stage.

At the outset, the Patent Office has rejected claims 74, 75 and 77 for alleged anticipation reasons in view of Galin I and further rejected these claims for alleged obviousness in view of Galin I and II. The anticipation rejection seems inconsistent with respect to the further alleged

obviousness rejection which was alleged in view of additional cited art (e.g., Galin II). Therefore, Applicant believes that the anticipation rejection is improper at least in view of same.

In any event, Applicant does not agree with the Patent Office position with respect to the cited art. For example, Galin I generally describes an ophthalmic solution that contains alpha-adrenergic blocking agents and further provides a list of six possible agents. Indeed, the preferred and only working example is directed to a solution that contains thymoxamine, and thus Galin I fails to recognize the benefits of the claimed ophthalmic night vision formulation with phentolamine. Moreover, the improved effect of a phentolamine-based solution on night vision as claimed, let alone phentolamine in an ophthalmic artificial tear solution as further defined in claim 76, should not be deemed an inherent property of the ophthalmic solution described in Galin I. Again, the preferred solution in Galin I is thymoxamine in purified water as detailed in the only working example, where further Galin I is directed to the use of alpha adrenergic blocking agents to aid in the fixation of intraocular lenses (See, Galin I, col. 1, lines 4-5) and not the effective reduction of pupil size to improve night vision as claimed.

Contrary to the Patent Office position, Applicant has conducted experiments as detailed in the specification which demonstrate the enhanced benefits to vision in dim light associated with the claimed phentolamine-based formulation as compared to other alpha-1 antagonist-based formulations. See, Applicant's Specification, Examples 1 and 2 and Tables 1 and 2, beginning on page 24. Such unexpected results are further supported by the Affidavit of Gerald Horn, M.D that was previously submitted in this case. Again, the claimed invention is directed to an ophthalmic formulation including an active compound consisting essentially of phentolamine. Indeed, the Table 1 data demonstrates that a phentolamine-based formulation has enhanced effects on pupil reduction and at a lower concentration than other types of alpha 1 antagonist-based formulations. This correlates with the Table 2 data, indicating improved vision in dim light due to enhanced pupil reduction. Therefore, Applicant does not believe Galin I provides sufficient teaching to render unpatentable the phentolamine-based ophthalmic solution that improves night vision as defined in presently pending claims 74-77.

Even assuming properly combinable, Galin II does not remedy the deficiencies of Galin I. At the outset, Galin II was merely relied on for its alleged teaching regarding the use of viscoelastic agents. Further, the Patent Office has mischaracterized Galin II. For example, Galin II is directed to "compositions which may be used to maintain structural integrity of the anterior

chamber of the eye and to provide sustained release of a miotic or mydriatic agent." See, Galin II, col. 2, lines 5-8. "In order to maintain the structural integrity of the anterior chamber of the eye, the compositions of [Galin II] must be sufficiently viscous such as to prevent the chamber from collapsing during surgical manipulation...[and] sufficiently fluid to permit their introduction into the anterior chamber by injection or extrusion...where the concentrations of viscoelastic polymer are preferably between about 10 mg/ml and 30 mg/ml..." See, Galin II, col. 7, lines 29-36. Clearly, the "viscous" composition in Galin II which is introduced into the anterior chamber by injection or extrusion contrasts with the claimed ophthalmic formulation that includes a phentolamine-based active compound in a sterile aqueous carrier, such as an artificial tear solution to "promote good wettability and spread" for administration to the corneal surface of the eye as further embodied in claim 76 and supported in the specification, for example, at paragraphs [0140] to [0146].

In light of the above, Applicant respectfully submits that the anticipation and obviousness rejections of Claims 74-77 are improper and should be reversed. If any additional fees are due in connection with this application as a whole, the Commissioner is authorized to deduct such fees from deposit account no. 02-1818.

Respectfully submitted,

K&L GATES LLP

BY _____

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Date: July 13, 2010